

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LAZAR, J. et al.

Group Art Unit: To be assigned

Serial No.: 09/707,178

Examiner: To be assigned

Filed: November 6, 2000

For: IMMUNOLOGICAL DETECTION OF RNA:DNA HYBRIDS ON MICROARRAY
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed ____.
4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or

- ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
- ☒ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
- ☐ 37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.
- ☐ Charge the fee to Deposit Account No. 13-4500, Order No. _____. A
DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. ☐ one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. ☐ the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);
- b. ☐ 37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).

- c. ☐ The fees due under 37 C.F.R. §§1.17(h) and 1.17(p) are paid as set forth in paragraph 11 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
10. ☐ This document is accompanied by ☐ a Search Report ☐ Communication which was cited in a corresponding ☐ PCT or ☐ Foreign counterpart application.
11. ☐ A check in the amount of \$ _____ is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).
- ☐ Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. 13-4500, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4020. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: June 3, 2002

By: _____

Dorothy R. Auth
Dorothy R. Auth
Registration No. 36,434

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

FORM PTO-1449 INFORMATION DISCLOSURE CITATION			Attorney Docket: 2629-4020		Serial No.: 09/707,178	
			Applicant: LAZAR, J. et al.			
			Filing Date: November 6, 2000		Group Art Unit: To be assigned	

U.S. PATENT DOCUMENTS							
Examiner Initial		Patent Number	Issue Date	Name	Class	Sub-Class	Filing Date
		6,232,068	5/15/01	Linsley et al.	435	6	1/22/99

FOREIGN PATENT DOCUMENTS							
Examiner Initial		Patent Number	Publication Date	Country	Class	Sub-Class	Translation
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No

OTHER DOCUMENTS (Including Author, Title, Date, etc.)		

Examiner	Date Considered
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 2629-4020		SERIAL NO. 09/707,178						
SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				APPLICANT LAZAR, J. ET AL.								
				FILING DATE November 6, 2000		GROUP TBA						
PATENT DOCUMENTS												
EXAMINER INITIAL			DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS												
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
										YES	NO	
	WO	99	2	9	9	0	9	A	June 17, 1999	PCT		
	WO	93	1	0	2	6	3	A	May 27, 1993	PCT		
	EP	02	8	8	7	3	7	A	November 2, 1988	PCT		
	WO	99	3	6	5	7	1	A	July 22, 1999	PCT		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.)												
EXAMINER								DATE CONSIDERED				
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.												

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EXAMINER INITIAL			DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	

FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
														YES	NO
	WO	97	3	1	2	5	6	A	August 28, 1997	PCT					
	WO	99	3	2	6	5	4	A	July 1, 1999	PCT					
	WO	99	3	9	0	0	1	A	August 5, 1999	PCT					
	WO	00	6	0	1	1	6	A	October 12, 2000	PCT					

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Papers, Etc.)</i>											

EXAMINER	DATE CONSIDERED
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PATENT DOCUMENTS														
EXAMINER INITIAL		DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
		4	7	3	2	8	4	7	Mar. 22, 1988	Stuart et al.				
		4	8	6	5	9	8	0	Sept. 12, 1989	Stuart et al.				
		5	8	2	7	6	6	1	Oct. 27, 1998	Blais				
		5	9	8	1	1	7	9	Nov. 9, 1999	Lorincz et al.				
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES	NO			
		9	9	4	0	2	2	4	August 12, 1999	PCT				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.)														
		Lazar et al., 1999 "Hybrid Capture @: a Sensitive Signal Amplification-based Chemiluminescent Test for the Detection and Quantitation of Human Viral and Bacterial Pathogens" <i>J. Clin. Ligand Assay</i> 22:139-151.												
		Coutlee et al., 1989 "Nonisotopic Detection of RNA in an Enzyme Immunoassay Using a Monoclonal Antibody Against DNA-RNA Hybrids" <i>Anal. Biochem.</i> 81:153-162.												
		Newman et al., 1989 "Solution Hybridization and Enzyme Immunoassay for Biotinylated DNA:RNA Hybrids to Detect Enteroviral RNA in Cell Culture" <i>Mol. Cell Probes</i> 3:375-382.												
		Lamoureux et al., 1997 "Detection of Campylobacter jejuni in Food and Poultry Viscera Using Immunomagnetic Separation and Microtitre Hybridization" <i>J. Appl. Microbiol.</i> 83:641-651.												
		Coutlee et al., 1990 "Quantitative Detection of Messenger RNA by Solution Hybridization and Enzyme Immunoassay" <i>J. Biol. Chem.</i> 265:11601-11604.												
		Stollar, B.D. and A. Rashtchian, 1987 "Immunochemical Approaches to Gene Probe Assays" <i>Anal. Biochem.</i> 161:387-394.												
EXAMINER							DATE CONSIDERED							
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
		6 0 2 7 8 9 7	Feb. 22, 2000	Lorincz					
		6 0 4 3 0 3 8	Mar. 27, 2000	Sivaraja et al.					
		4 8 3 3 0 8 4	May 23, 1989	Carrico					

FOREIGN PATENT DOCUMENTS									
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
							YES	NO	

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Papers, Etc.)</i>		
		Blais, B.W., 1994 "Transcriptional Enhancement of the <i>Listeria Monocytogenes</i> PCR and Simple Immunoenzymatic Assay of the Product Using Anti-RNA:DNA Antibodies" <i>Appl. Environ. Microbiol.</i> 60:348-352.
		Coutlee et al., 1991 "Detection of Transcripts of Human Papillomaviruses 16 and 18 in Cancer-derived Cell Lines and Cervical Biopsies by Enzyme Immunoassay for DNA-RNA Hybrids Following Solution Hybridization" <i>J. Clin. Microbiol.</i> 29:968-974.
		Viscidi et al., 1989 "Monoclonal Antibody Solution Hybridization Assay for Detection of Human Immunodeficiency Virus Nucleic Acids" <i>J. Clin. Microbiol.</i> 27:120-125.
		Boguslawski et al., 1986 "Characterization of Monoclonal Antibody to DNA:RNA and Its Application to Immunodetection of Hybrids" <i>J. Immunol. Methods</i> 89:123-130.
		Coutlee et al., 1989 "Immunodetection of DNA with Biotinylated RNA Probes: A Study of Reactivity of a Monoclonal Antibody to DNA-RNA Hybrids" <i>Anal. Biochem.</i> 181:96-105.
		Coutlee et al., 1991 "Immunodetection of DNA with Biotinylated RNA Probes: A Study of Reactivity of a Monoclonal Antibody to DNA-RNA Hybrids" <i>Anal. Biochem.</i> 198:217 (Published erratum).
		Coutlee et al., 1989 "Comparison of Colorimetric Fluorescent, and Enzymatic Amplification Substrate Systems in an Enzyme Immunoassay for Detection of DNA-RNA Hybrids" <i>J. Clin. Microbiol.</i> 27:1002-1007.

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